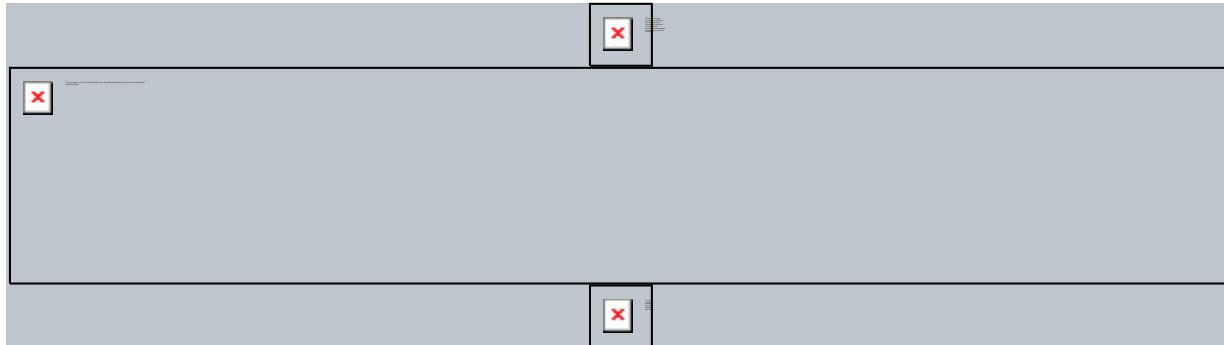


Sanjabi, Bardia (Assoc-ATL-LT)

From: Drug Daily Bulletin (External) <enewsletters@fdanews.com>
Sent: Tuesday, July 11, 2017 2:05 AM
To: Marc Falkin
Subject: Pacira Shuts DepCyt Operations After Years of Manufacturing Problems [MARKETING]

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Principles of Equipment Qualification

This report — authored by international GMP expert Thomas Peither and associates — lays out the basics of building a four-phase qualification plan... design qualification, installation qualification, operational qualification and performance qualification... that satisfies US and EU requirements. [Order today](#).

Pacira Shuts DepCyt Operations After Years of Manufacturing Problems

Unable to resolve persistent manufacturing problems, New Jersey-based drugmaker Pacira Pharmaceuticals is ending production of its DepoCyt chemotherapy drug and closing the California plant where it is made.

Pacira informed the FDA, EMA, Health Canada and drug distribution partners Leadiant and MundiPharma of the move June 29, the same day the company filed an 8K “special events” notice with the U.S. Securities and Exchange Commission.

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FDA Approves First New Sickle Cell Drug in 20 Years

The FDA on Friday approved Endari, the first new drug in nearly 20 years to treat sickle cell anemia complications.

The L-glutamine oral powder, sponsored by Emmaus Medical, was approved for adults and children over 5 years old to reduce severe complications associated with the blood disorder. Previously, the only available treatment was hydroxyurea, approved by the FDA in 1998.

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How to Build a Risk Management Strategy for Compliance Management Systems

When looking at the dynamic of business, from any industry, there is an increasing rate of change. Changes in products, processes, and regulations are all driving each other. With increasing oversight on compliance regulations and standards, complexity becomes a growing theme, whether in Quality Management or general compliance. In this white paper learn about how compliance is necessary, and it can be a significant investment on an organization. [Download now](#)

AAM Sues Maryland to Block Generic Drug Price Gouging Law

The Association for Accessible Medicines filed a lawsuit against the attorney general of Maryland, hoping to block the state's recently passed law ostensibly banning generic drug price gouging.

Formerly known as GPhA, the AAM said the effects of the new law will extend past Maryland's borders, running afoul of the Constitution's interstate commerce clause, and that manufacturers and distributors do not make pricing decisions on a state-by-state basis.

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PTAB Invalidates AbbVie's Humira Dosing Patent — Again

The PTO's Patent Trial and Appeal Board once again ruled that a patent for AbbVie's Humira was invalid and unpatentable, responding to additional challenges by Boehringer Ingelheim.

In May, the PTAB ruled the patent — which covers dosing methods for anti-tumor necrosis factor alpha antibodies, such as Humira (adalimumab), for the treatment of rheumatoid arthritis — was considered obvious based on materials submitted by Coherus Biosciences. The patent includes a subcutaneous dosing regimen of 40 mg once every two weeks.

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Texas Pharmacy Warned on Sterility and More

A complaint about ineffective erectile dysfunction drugs launched an FDA inspection of a compounder operated by a Texas-based pharmacy chain, leading to a lengthy warning letter from the agency detailing sterility concerns.

In addition to the pharmacy's lack of valid prescriptions for some of its prepared drugs, FDA inspectors found "serious deficiencies" in sterility practices at Dougherty's Pharmacy Preston Royal location in Dallas.

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